

Claim Objections

1. Claim 1 is objected to because of the following informalities: “an analyte detecting members” should read as either “a plurality of analyte detecting members” or “an analyte detecting member”. Appropriate correction is required.
2. Claim 2 is objected to because of the following informalities: “to form texturing” should be cancelled from the claim, since the limitation is not necessary. Appropriate correction is required.
3. Claim 6 is objected to because of the following informalities: “the penetrating member driver” lacks antecedent basis in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed method steps fail to comply with the requirements set forth in the decision of *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008). The steps are not tied to any particular structure for performing the claimed method. Furthermore, the claimed steps could be performed by a person performing manual calculations.

Claim Rejections - 35 USC § 102

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5 and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Boecker et al (2004/0098009 A1).

Boecker et al disclose a means for body fluid sampling and analysis and further disclose a single cartridge; a penetrating member coupled to the single cartridge; an analyte detecting member; providing a single cartridge configured to slidably hold a plurality of penetrating members and to have a plurality of analyte detecting members; using surface texturing to direct fluid into a desired area on the cartridge (wickings elements, etc); the texturing is formed chemically (printing on the surface to produce an analyte detection surface requires a chemical reaction); the texturing guides the fluid to one of the analyte detecting members; a plurality of penetrating members coupled to the single cartridge and operatively couplable to a penetrating member driver, the penetrating members movable to extend radially outward from the cartridge to penetrate tissue; a support structure; a sensory material on a first side of the support structure; a conductor material coupled to the sensory material; a commutator positioned to engage the conductor material to obtain analyte measurements; a radial cartridge, the support structure coupled to the radial cartridge; and a plurality of electrodes, each having the

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sensory material. See Figures 1 and 2; Paragraphs 0006, 0007, 0142, 0143, 0176 and 0184.

7. Claims 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Boecker et al (2004/0093995 A1).

Boecker et al disclose a fluid sampling and analyte sensing means and further disclose a single cartridge; a plurality of penetrating members coupled to the single cartridge and operatively couplable to the penetrating member driver; the penetrating members movable to extend radially outward from the cartridge to penetrate tissue; a plurality of analyte detecting members coupled to the single cartridge, wherein at least one of the analyte detecting members positioned on the cartridge to receive body fluid from a wound in tissue created by the penetrating member when the cartridge in an operative position; a plurality of mesh structures positioned to draw fluid generated by the tissue towards one of the analyte detecting members; a ring around the cartridge wherein the analyte detecting members are mounted on the ring, along with the mesh; a ring around the cartridge wherein the analyte detecting members are coupled to the cartridge through the ring; and a plurality of electrodes coupled to the analyte detecting member. See Figures 1, 2 and 73-78; Paragraphs 0173, 0179, 0184 and 0230.

8. Claims 14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubowsky et al (2003/0210811 A1).

Dubowsky et al disclose an actuator, and further disclose a support structure; a first electrode; a second electrode; an elastomeric material between the electrodes, wherein the material elongates upon activation of the electrodes, causing a penetrating

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member to move; and a coupler in contact with the material for coupling the penetrating member to the material (needle 2244 is connected to the elastomeric actuator, thus requiring some sort of a "coupler" to connect the needle to the material). See Paragraphs 0005, 0011 and 0143.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubowsky et al (2003/0210811 A1) as applied to claim 14 above, and further in view of Boecker et al (2004/0098009 A1).

Dubowsky et al, as discussed above, disclose an actuator assembly, but fail to teach a radial cartridge, the material having a gripper to engage penetrating members on the radial cartridge.

Boecker et al, as discussed above, disclose a fluid sampling and analysis device and further disclose a radial cartridge, the actuating element having a gripper to engage penetrating members on the radial cartridge. See Figure 1; and Paragraphs 0142 and 0143.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Dubowsky et al to include a radial cartridge

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with a plurality of penetrating members for fluid analysis and a gripper coupled to the actuating element to engage a penetrating member, as per the teachings of Boecker et al, since it would provide an alternative means of actuating the penetrating member to penetrate the tissue to acquire a fluid sample other than through the use of a mechanical means using springs and gears, and through the use of an electrical actuator for actuating the penetrating member.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Brian Szmal/
Examiner, Art Unit 3736